IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE: ARNTZEN, Charles T. et al.	)
	) **APPEAL NO. _____**
SERIAL NO: 10/733,135	)
	)
FOR: VACCINES EXPRESSED IN PLANTS	) **SUPPLEMENTAL**
	) **REPLY BRIEF**
FILED: December 11, 2003	)
	)
GROUP ART UNIT: 1638	)

To the Commissioner of Patents and Trademarks
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Dear Sirs and Madams:

In response to the Supplemental Examiner's Answer dated July 21, 2009, please enter the following Supplemental Reply Brief on Appeal into the record under 37 CFR 41.41.

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Janaé E. Lehman Bell, Ph.D.

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I. INTRODUCTION

In accordance with 37 CFR 41.41, the Appellants submit herewith a Supplemental Reply Brief in response to the Supplemental Examiner's Answer dated July 21, 2009 in the above-identified U.S. patent application. Appellants submit the Supplemental Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated July 15, 2008, the Examiner's Answers of January 29, 2009 and March 29, 2009 as noted herein, in the Appellants' Appeal Brief of November 17, 2009, and in Appellant's first reply brief of March 18, 2009. Appellants respectfully request that the rejections to claims 1-10 be reversed.

II. STATUS OF CLAIMS

Claims 1-14 were originally submitted December 11, 2003. In a Response to Office Action (Restriction Requirement) dated October 5, 2006, Appellant elected Group I (claims 1-10) and claims 11-14 were withdrawn. In an amendment dated June 20, 2007, Appellant amended claims 1, 4 and 8-10. In an Amendment accompanying a Request for Continued Examination filed October 31, 2007, Appellant amended claims 1, 6 and 8-9 and added claims 15-16. In an Amendment filed March 26, 2008 Appellant canceled claims 11-16. The final rejection mailed July 15, 2008 reinstated the rejections to claims 1-5 and 7-10 as obvious over Goodman et al. (U.S. Patent No. 4,956,282, issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546) and to claim 6 as obvious over Goodman et al. (U.S. Patent No. 4,956,282 issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546), as applied to claims 1-5 and 7-10 above, and further in view of Kay et al. (Science (1987), Vol. 236, pp. 1299-1302), and further in view of Gallie et al. (MGG (1991), Vol. 228, pp. 258-264). The claims here appealed are claims 1-10.

III. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1-5, 7-8 and 10 are unpatentable over Goodman et al. (U.S. Patent No. 4,956,282, issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546).

B. Whether claims 6 and 9 are unpatentable over Goodman et al. (U.S. Patent No. 4,956,282 issued September 11, 1990) in view of Kapikian et al. (Reviews of Infectious Diseases (1989) Vol. 11, supplement 3, pp. S539-S546), as applied to claims 1-5 and 7-10 above, and further in view of Kay et al. (Science (1987), Vol. 236, pp. 1299-1302), and further in view of Gallie et al. (MGG (1991), Vol. 228, pp. 258-264).

IV. ARGUMENT

A. The § 103 Rejection Based Upon Goodman et al. and Kapikian et al. Has Been Improperly Maintained

1. Goodman et al. and Kapikian et al. Fails to Provide a Reasonable Expectation of Success for Appellants' Claimed Method

The cited references provide no reasonable expectation of success for Appellants' claimed methods. Neither of these references provide any reasonable expectation that a viral immunogen could be expressed in a plant, orally administered to an animal, survive the animal's gut, and provide the animal protection against subsequent viral challenge. The Examiner's position that there is a reasonable expectation of success is unsupported and the obvious rejection improper.

The Examiner's writes that the viral protein VP7 is the major neutralization protein of a human rotavirus belonging to serotypes 1, 2, or 4 and that a hybrid or reassortment virus can be generated via reassortment with a human and a rhesus rotavirus. Supplemental Examiner's Answer, at page 3. The Examiner concludes that "[t]his suggests that having only one of the neutralizing proteins is sufficient for generating an immune response." Supplemental Examiner's Answer, at page 3. The Examiner, however, misconstrues the teachings of Kapikian et al. to mean that one neutralizing protein such as VP7 is sufficient for generating an immune response outside the context of rotavirus expression. To the contrary, the Kapikian reference's entire discussion of reassortment rotaviruses assumes the exchange and expression of viral genes between closely related rotaviruses, for example, single-gene substitutions of VP7 between human and animal rotaviruses. Kapikian et al., at page S543, right column. These different rotaviruses all share common characteristics of a double-layer capsid comprising the inner-capsid polypeptides of VP1, VP2, and VP6 and the outer-layer capsid polypeptides of VP3 and VP7. Kapikian et al., at page S541, right column. Accordingly, when human VP7 is exchanged for rhesus or bovine VP7 in the hybrid rotavirus, VP7 polypeptide still

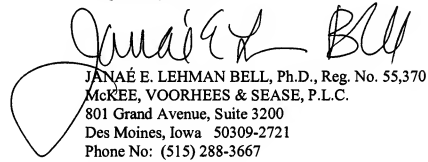
combines with VP3 to form the outer layer of the capsid. The fact that human VP7 maintains its antigenicity in this context provides no expectation of success that VP7 would maintain antigenicity when expressed alone or in plant cells because it would be expressed and presented to the recipient's immune system independently of the virus.

The Examiner writes that because the viral particle is not infective, it only serves as a carrier. While the viral particle is not infectious, this does not diminish the importance of the viral capsid protein-protein interactions with one another or indicate that the intact native conformation of the vial particle is inconsequential in generating an immune response. Given the interaction of the VP7 with VP3, antigenicity may be due to discontinuous epitopes on surface resides of VP7 and VP3 that are brought together by their proper folding and interaction with one another. Thus, it cannot be concluded from Kapikian et al. that the viral particle is simply a carrier and that one neutralizing protein such as VP7 on its own would be sufficient for generating an immune response. Thus, Kapikian at el. provide no reasonable expectation of success that a viral immunogen expressed in a plant and administered orally would generate an immune response, much less a protective immune response that could protect against viral challenge. Therefore, the claimed invention is not obvious. For all these reasons and those previously made of record, Goodman et al. and Kapikian et al. do not provide a reasonable expectation of success for a method of making an immunogenic composition comprising a plant-expressed recombinant viral immunogen that elicits an immunogenic response when orally administered to an animal and protects the animal against viral challenge. For at least these reasons, independent claims 1 and 8 and dependent claims 2-5, 7 and 10 are patentable over Goodman et al. and Kapikian et al. The Examiner's rejection to these claims under § 103 rejection should be reversed.

V. CONCLUSION

In view of the foregoing, Appellants respectfully submit that the Examiner's Supplemental Answer does not remedy the deficiencies noted herein and in Appellants' Appeal Brief and Appellants' Reply Brief. The Examiner's rejections under § 103 remain improper and should be reversed by the Board. It is respectfully submitted that the claims are in condition for allowance and the case should be allowed. No fees or extensions of time are believed to be due in connection with this Replay Brief; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



JANAÉ E. LEHMAN BELL, Ph.D., Reg. No. 55,370
McKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO:
Attorneys of Record